REMARKS

At page 2 of the Office Action, claims 1-42 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-79 of US 6,323,180. The Examiner asserts that the claims are not patentably distinct from each other "because both are drawn to the same essential invention . . .".

Applicants respectfully disagree with the Examiner's conclusion. The claims of the '180 patent and the claims of the present application are not drawn to the same invention.

The claims of the '180 patent are directed to the HCV inhibitor compounds of formula (I), pharmaceutical compositions thereof, methods for their preparation, and method for their use in the treatment of HCV infection. The pharmaceutical composition claim of the '180 patent is claim 65 which recites a compound of formula (I), or a therapeutically acceptable salt or ester thereof, in admixture with a pharmaceutically acceptable carrier medium or auxiliary agent. The types of pharmaceutical compositions that are covered by claim 65 of the '180 patent, and the carrier mediums and auxiliary agents that are contemplated, are described in detail at col. 26, lines 25-59 of the '180 patent. These are conventional pharmaceutical formulations containing conventional carriers and auxiliary agents.

By contrast, claims 1-42 of the present application are drawn to certain specific pharmaceutical compositions of the anti-HCV compounds of formula (I), and methods for their manufacture and use, wherein all such claimed compositions comprise a compound of formula (I) together with at least one or more pharmaceutically acceptable amines. See the recitation of pharmaceutically acceptable amines, for example, in claims 1, 4 and 5. In addition, the lipid-based system compositions of the present invention all require the presence of one or more pharmaceutically acceptable oils. See the recitation of oils in claims 1, 7 and 8. Thus, the amine-based pharmaceutical compositions claimed in the present application are clearly different from the conventional pharmaceutical compositions that are claimed in the '180 patent, and there is no teaching or suggestion found in the '180 patent to specifically modify the conventional compositions therein claimed to include one or more amines and/or oils and the Examiner has failed to identify any other prior art that would have taught or suggested such modification.

As clearly set forth in MPEP § 804, Section II B 1, regarding the nonstatutory obviousness-type double patenting rejection:

> A double patenting rejection of the obviousness-type is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103" except that the patent principally underlying the double patenting rejection is not considered prior art. *In re Braithwaite*, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).
>
> . . .
>
> Any obviousness-type double patenting rejection should make clear:
>
> (A) The differences between the inventions defined by the conflicting claims - a claim in the patent compared to a claim in the application; and
>
> (B) The reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim in issue is an obvious variation of the invention defined in a claim in the patent.

In view of the above, it is clear that the Examiner has failed to establish a *prima facie* case of nonstatutory obviousness-type double patenting, in accordance with established precedent and the MPEP guidelines. The Examiner has not acknowledged and identified the clear differences between the claimed inventions and has not provided reasons, supported by acceptable evidence, as to why a person of ordinary skill in the art would conclude that the invention defined in the present claims is an obvious variation of the invention defined in a claims of the patent '180 patent. In this context, the Examiner has not identified any disclosure in the '180 patent itself or in any other prior art reference that would have provided a specific teaching, suggestion or motivation for a person skilled in the art to modify the pharmaceutical compositions of the '180 patent in the manner necessary to arrive at the presently claimed amine-based pharmaceutical compositions, let alone with any reasonable expectation of success. See also MPEP § 2143 "Basic Requirements of a *Prima Facie* Case of Obviousness". The Examiner has not established the basic requirements necessary to support a *prima facie* case of obviousness over the claims of the '180 patent.

Accordingly, Applicants respectfully submit that this obviousness-type double patenting rejection is improper and should be withdrawn.

Applicants filed an Information Disclosure Statement (IDS) in this application on February 23, 2004 (copy enclosed), but have not yet received any acknowledgment of this filing. The Examiner is kindly requested to return an initialed and signed copy of the PTO-1449 form filed with said IDS to confirm that the cited references were considered by the Examiner.

In view of the above amendments and remarks, Applicants respectfully submit that this application is now in condition for allowance and earnestly request such action.

If any points remain at issue which can best be resolved by way of a telephonic or personal interview, the Examiner is kindly requested to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,

Philip I. Datlow
Attorney for Applicant(s)
Reg. No. 41,482

Patent Department
Boehringer Ingelheim Corp.
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT. 06877
Tel.: (203) 798-4542
June 4, 2004